

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Previously presented) A topical formulation comprising:
at least about 25% of nutmeg oil containing an intrinsic menthol component, and
added menthol in an amount of at least about 0.1% by weight,
the total menthol being in the range of 0.2% to 16% of the formulation by weight.
2. (Previously presented) The formulation of claim 1, wherein the nutmeg oil is prepared
from *Myristica fragrans*.
3. (Previously presented) The formulation of claim 1, wherein the nutmeg oil is prepared
by steam distillation.
4. (Previously presented) The formulation of claim 1, wherein the nutmeg oil is non-
irritating nutmeg oil, containing less than about 5% of myristicin and less than about 0.5% of
safrole.
5. (Previously presented) The formulation of claim 1, wherein the nutmeg oil is
complete nutmeg oil, comprising intrinsic menthol, β -citronellol, bornyl acetate, and 1-t-
carophyllene.
6. (Previously presented) The formulation of claim 1, wherein the formulation
comprises about 50% to about 99% nutmeg oil by weight, and about 0.2% to about 16%
total menthol by weight.
7. (Previously presented) The formulation of claim 1, wherein the formulation
comprises about 84% to about 99% nutmeg oil by weight, and about 0.2% to about 16%
total menthol by weight.

8. (Previously presented) The formulation of claim 1, wherein the formulation consists essentially of nutmeg oil and added menthol.
9. (Previously presented) The formulation of claim 1, wherein the total menthol is about 0.2% to about 1.0%
10. (Previously presented) The formulation of claim 1, wherein the total menthol is about 2 %.
11. (Previously presented) The formulation of claim 1, wherein the total menthol is about 1.25% to about 5%.
12. (Previously presented) The formulation of claim 1, wherein the total menthol is about 5% to about 10%.
13. (Previously presented) The formulation of claim 1, wherein the total menthol is about 10% to about 16%.
14. (Previously presented) The formulation of claim 1, wherein the formulation consists essentially of nutmeg oil and added menthol, the added menthol being about 2% by weight.
15. (Previously presented) The formulation of claim 1, being effective to relieve pain when applied topically to a subject.
16. (Previously presented) The formulation of claim 1, further comprising a container holding the formulation, and labeling associated with the container indicating use for treatment of pain.
17. (Previously presented) The formulation of claim 16, wherein the labeling indicates

use for one or more of temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, bruises, sprains and strains; temporary relief of pain associated with rheumatism; temporary relief of aches and pains of muscles and joints associated with over-exercising & sports injuries; temporary relief of pain associated with bursitis, body aches and cramps; topical pain relief; topical fast acting pain relief, topical targeted pain relief; massage therapy; aches and pain associated with seniors; adjunct treatment of physical therapy; prescription drug and over the counter medication.

18. (Previously presented) The formulation of claim 1, wherein the formulation comprises about 0.2% to about 1.0% total menthol, and the formulation is effective for the temporary relief of pain and/or itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and/or minor skin irritations.
19. (Previously presented) The formulation of claim 1, wherein the formulation further comprises a non-nutmeg essential oil in an amount of less than about 2%.
20. (Previously presented) The formulation of claim 19, wherein the non-nutmeg essential oil comprises pimento berry (allspice) oil.
21. (Previously presented) The formulation of claim 1, wherein the nutmeg oil and added menthol are effective to relieve pain without additional non-menthol analgesics.
22. (Previously presented) A method for treating pain comprising administering to a patient, topically, a pain relieving formulation comprising nutmeg oil and added menthol in an amount effective to relieve pain, without administering other topical analgesics.
23. (Currently Amended) A method for producing a topical formulation comprising:
selecting a target menthol level for the formulation in the range of 0.42% to 16% w/w,
obtaining nutmeg oil,

determining the amount of menthol equivalent in the intrinsic menthol component in the nutmeg extract, and

~~if the amount of menthol equivalent is less than the target menthol level,~~ adding extrinsic menthol to make up the difference, between the amount of menthol equivalent and the target menthol level,

the total amount of menthol being in the range of 0.12% to 16%.

24. A pharmaceutical preparation comprising a container comprising at least about 25% nutmeg oil, the oil being non-irritating, and the preparation containing a predetermined concentration of menthol in the range of 0.1% to 16%, associated with labeling indicating use for relief of pain.